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#15

February 27, 1989

Mr. Ronald Wilson  
Office of the Associate Commissioner  
for Health Affairs (HFY-20)  
Room 11-46  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

RE: Optiray  
FDA Docket # 89E-0055

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for Patent Extension of U.S. Patent No. 4,396,598, issued August 2, 1983. The application was filed on February 9, 1989 under Title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product and method of using a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination of the applicable regulatory review period is necessary. Accordingly, notice a copy of the application are provided pursuant to 35 USC 156(d)(2)(A).

*C. E. Van Horn*

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Deputy Solicitor  
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